

**AMENDMENT**

**IN THE CLAIMS:**

Please amend the claims as follows:

1-3. (Canceled)

4. (Currently amended) A microfluidized lysate preparation ~~free of dextran and comprises~~  
consisting of

an amount of a microfluidized slurry of at least one *Leishmania* parasite strain;

TWEEN-80;

glycerol;

phenol; and

saline ~~and does not cause a false positive type I hypersensitivity reaction when~~  
~~administered to a human subject.~~

5-10. (Canceled)

11. (Original) A kit comprising the microfluidized lysate preparation of claim 4 and directions for determining whether a subject has been exposed to a *Leishmania* parasite or was afflicted with Leishmaniasis.

12. (Previously presented) The kit of claim 11, wherein the *Leishmania* parasite strain is *L. tropica*, *L. mexicana*, *L. guyanensis*, *L. braziliensis*, *L. major*, *L. donovani*, *L. chagasi*, *L. amazonensis*, *L. peruviana*, *L. panamensis*, *L. pifanoi*, *L. infantum*, or *L. aethiopica*.

13-21. (Canceled)

22. (Previously presented) The microfluidized lysate preparation of claim 4, and further comprising a pharmaceutically acceptable stabilizer.

23. (Previously presented) The microfluidized lysate preparation of claim 22, wherein the pharmaceutically acceptable stabilizer is phenol.

24. (Previously presented) The microfluidized lysate preparation of claim 22, wherein the microfluidized lysate preparation is in the form of a liquid.

25. (Previously presented) The microfluidized lysate preparation of claim 22, wherein the microfluidized lysate preparation may be frozen or freeze-dried.

26-28. (Canceled)

29. (Previously presented) The microfluidized lysate preparation of claim 4, wherein the microfluidized lysate preparation is heat treated.

30. (Previously presented) The microfluidized lysate preparation of claim 4, wherein the *Leishmania* parasite strain is *L. tropica*, *L. mexicana*, *L. guyanensis*, *L. braziliensis*, *L. major*, *L. donovani*, *L. chagasi*, *L. amazonensis*, *L. peruviana*, *L. panamensis*, *L. pifanoi*, *L. infantum*, or *L. aethiopica*.

31. (Canceled)

32. (Previously presented) The microfluidized lysate preparation of claim 4, wherein the microfluidized slurry was made by passing the *Leishmania* parasite strain through a chamber and disrupting the *Leishmania* parasite strain with a sudden release of pressure.

33-34. (Canceled)

35. (New) The microfluidized lysate preparation of claim 4, wherein the amount of the microfluidized slurry of at least one *Leishmania* parasite strain is  $0.35 \pm 0.05$  mg/ml.

36. (New) The microfluidized lysate preparation of claim 4, wherein the TWEEN-80 is at a concentration of 0.001%.

37. (New) The microfluidized lysate preparation of claim 4, wherein the glycerol is at a concentration of 1%.

39. (New) The microfluidized lysate preparation of claim 4, wherein the phenol is at a concentration of 0.4%.

40. (New) A microfluidized lysate preparation consisting of  
0.35  $\pm$  0.05 mg/ml of a microfluidized slurry of at least one *Leishmania* parasite strain;  
0.001% TWEEN-80;  
1% glycerol;  
0.4% phenol; and  
saline.